

## AMENDMENTS TO THE SPECIFICATION

*Please add the following paragraph before "Field of the Invention" on page 1 of the Application as filed:*

B1  
This application claims priority to provisional application serial no. 60/193,181, filed on March 30, 2000, which is incorporated herein by reference in its entirety.

*Please replace the paragraph beginning at page 14, line 35, with the following:*

B2  
The primary efficacy endpoint for the study was the change in total symptom score between baseline and week 6. The primary analysis of efficacy was an intent-to-treat analysis where all patients who were randomized to one of the three treatments and had at least ~~one~~ one post-randomization assessment (including SAQ and IAQ) were included. Of the 89 patients who were randomized, two ~~patients~~ patients (04/002 and 05/919) were excluded because there were no data to assess efficacy collected after they are randomized.

*Please replace the paragraph beginning at page 15, line 4, with the following:*

B3  
The secondary analysis of efficacy was a "per protocol" analysis which included all patients who completed the study per protocol. This per protocol analysis was performed only for the primary efficacy endpoint, i.e., the change from baseline to the end of the study in the total symptom score. Patients who did not meet the baseline SAQ/IAQ score criteria were excluded. The SAQ and IAQ taken during the time ~~interval~~ interval in which prohibited concomitant therapies were taken was also excluded from the per protocol analysis. The statistical analysis results for the Individual Symptom Score analysis and for the per protocol analysis are provided in Table 1 and Table 2, respectively.

*Please replace the paragraph beginning at page 22, line 3, with the following:*

B4  
The mean observed accumulation, determined as the ratio of the  $AUC_{0-\tau}$  on day 42 to the  $AUC_{0-\tau}$  on day 1, for a given treatment group were 1.95 (range: 0.96 - 4.47), 2.55 (range: 0.29 - 19.04) and 1.89 (range: 0.07 - 6.35), for the 10 mg oral, 10 mg nasal spray and the 20 mg nasal spray, respectively. These ~~ratio's~~ ratios indicate that at steady-state, the average plasma concentration of metoclopramide is approximately twice that following a single dose administration.